BLOOD FLOW MEASUREMENT METHOD IN HEMODIALYSIS SHUNTS

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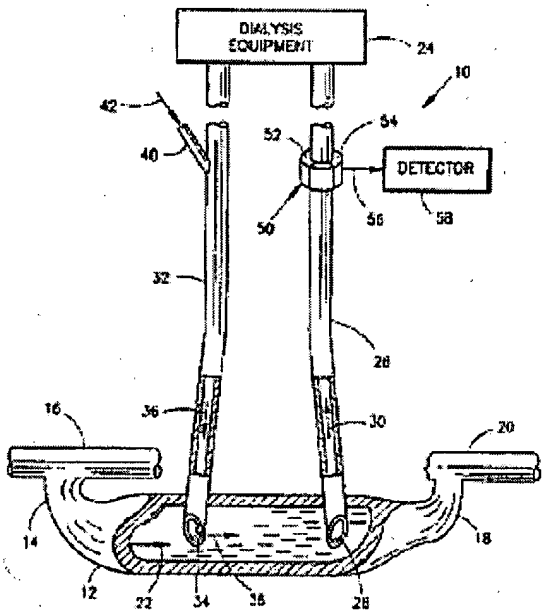
The measurement of blood flow in a dialysis shunt is obtained by injection of an indicator material into a venous line leading from dialysis equipment to the shunt. The blood flow in an arterial line leading from the shunt at a location downstream of the venous line to the dialysis equipment is monitored by an arterial line sensor for the presence of the indicator material. A detector connected to the sensor provides a dilution curve in response to the presence of the indicator material and the blood flow in the shunt is calculated from the area under the dilution curve. The locations of the arterial and venous lines in the shunt can be reversed to obtain a measurement of blood recirculation from the venous line into the arterial line.



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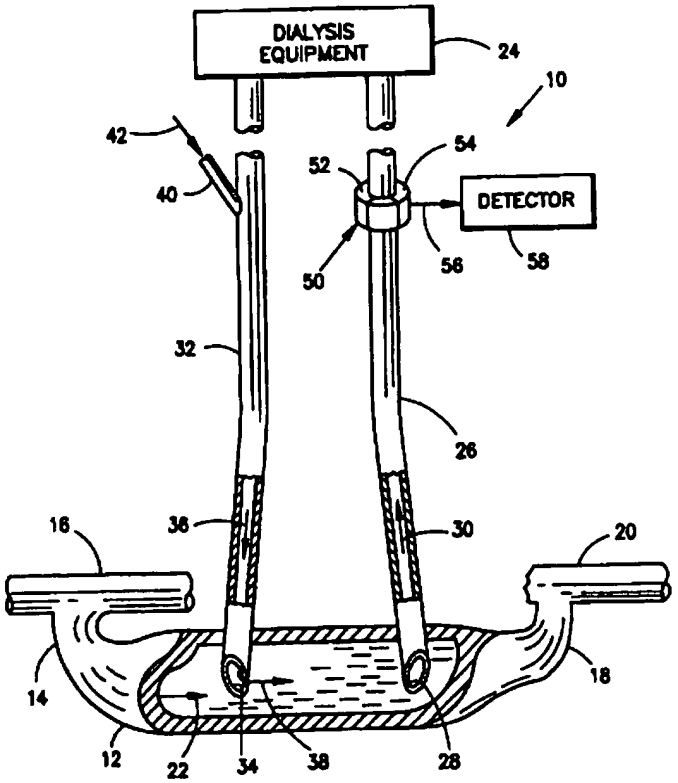
(57) Abstract

The measurement of blood flow in a dialysis shunt (12) is obtained by injection of an indicator material into a venous line (32) leading from dialysis equipment (10) to the shunt (12). The blood flow in an arterial line (26) leading from the shunt (12) at a location downstream of the venous line (32) to the dialysis equipment (10) is monitored by an arterial line sensor (50) for the presence of the indicator material. A detector (58) connected to the sensor (50) provides a dilution curve in response to the presence of the indicator material and the blood flow in the shunt (12) is calculated from the area under the dilution curve. The locations of the arterial and venous lines (26, 32) in the shunt (12) can be reversed to obtain a measurement of blood recirculation from the venous line (32) into the arterial line (26).



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BLOOD FLOW MEASUREMENT METHOD IN HEMODIALYSIS SHUNTS

Background of the Invention

The invention relates to the field of kidney dialysis processes and more particularly to such processes for measuring arterio-venous shunt blood flow and undesirable recirculation during hemodialysis.

Dialysis is a process by which an artificial kidney replaces the function of a patient's kidney. Blood is removed from the patient's vascular system via an arterial line, is passed through a dialyzer and is returned to the patient via a venous line for normal circulation through the patient's vascular system. A majority of dialysis patients have an arterio-venous shunt implanted in a location having a high blood flow that simplifies the withdrawal of blood from the part that is closer to the arterial side of the shunt and the return of purified blood downstream of the withdrawal site, closer to venous side of the shunt. In some cases the shunt clots or stenoses and the resulting reduction in blood flow necessitates surgery that is costly and invasive for the patient. In the situation of low blood flow in the shunt or, if there is any other problem with the venous outflow, some part of the freshly dialyzed blood from the venous return line flows directly to the arterial withdrawal line where it is again filtered. If this undesired direct recirculation level is high enough, some amount of blood will be repeatedly refiltered and the rest of the patient's blood will not be sufficiently filtered to provide the patient with adequate dialysis.

One method of measuring shunt blood flow currently uses color coded duplex sonography. This is very expensive and involves operation by highly-qualified professionals. Measurements are therefore made only rarely and the onset of reduced flow, when treatment could be made without surgery, can be missed.

The standard test for undesired direct recirculation requires three blood samples while the patient is on dialysis. This method requires blood samples from the patient, time from the nurses, and high laboratory costs. Dialysis patients generally have lower hematocrit than the normal population and are at greater risk from losing blood, so this is not very satisfactory.

Another technique involves injection of a saline solution intravenously and recording changes of blood optical properties for detecting recirculation qualitatively. This technique leaves open the question of whether recirculation is quantitatively reduced sufficiently to warrant intervention.

Summary of the Invention

The present invention avoids the problems encountered with previous methods and techniques by providing an accurate determination of shunt blood flow and undesired recirculation at lower cost.

Blood flow, Q, measured by the dilution method (A.C. Guyton Textbook of Medical Physiology, Sixth Edition, p. 287, 1981) is given by:

$$Q = V / S \qquad \text{(Eq. 1)}$$

where V is the amount of injected indicator and S is the area under a dilution curve and is equal to the average concentration of indicator in the blood for the duration of the curve, multiplied by the duration of the curve.

A dilution curve is obtained by measuring changes in a physical parameter of the blood over a period of time, and plotting the resulting variations. For example, if the blood parameter being measured is sound velocity, the injection of an indicator such as a saline solution, having a different sound velocity than blood, will produce a change in the measured parameter as the indicator passes the sensor location. The indicator dilutes the blood, and produces a sound velocity curve which is a measure of that dilution. Although injection of a saline solution is convenient for producing a measurable change in a blood parameter such as sound velocity, other changes of parameters may also be suitable. Thus, changes in temperature, electrical impedance, optical characteristics, and the like may also be used as indicators to produce dilution curves. For purposes of this disclosure, however, reference will primarily be made to the use of saline solution as the indicator, with resulting changes in sound velocity in the blood being measured to provide a dilution curve.

To facilitate the measurement of shunt blood flow in accordance with the present invention, the blood line connection is reversed from normal; that is, the arterial inlet which removes the blood from the patient for dialysis is located

downstream (not upstream as normal) of the venous outlet in the shunt. A volume of indicator, such as a saline solution, is injected into the venous line (V_{ven}), where it is mixed with the dialyzer blood flow Q_{dial} and the mixture is delivered to the shunt where it is combined with the blood flow in the shunt (Q_{shunt}). The blood shunt flow (Q_{shunt}) can be calculated from Equation 1 by measuring the dilution area in the arterial line S_{art}:

$$Q_{shunt} + Q_{dial} = V_{ven} / S_{art} \quad \text{(Eq. 2)}$$

or

$$Q_{shunt} = V_{ven} / S_{art} - Q_{dial} \quad \text{(Eq. 3)}$$

Equation 3 shows that if the blood flow through the dialyzer Q_{dial} is measured and the absolute concentration of indicator in the arterial blood line S_{art} is recorded, then the blood flow through the shunt Q_{shunt} can be calculated.

In some methods applicable to hemodialysis, sensors are clamped onto the exterior of the arterial or venous line, or tube. However, it is difficult to measure the absolute concentration of indicator in the blood through the hemodialysis tube. For example, if a sound velocity sensor is used to record protein concentration changes in blood due to a saline indicator injection, the sound beam will have to pass through both the tube and the blood. Recorded measurements of absolute sound velocity will be influenced not only by the blood, but also by the unknown sound properties of the tube. The same problem occurs if an optical sensor is clamped onto tube; i.e., the recorded amplitude

of a light beam is not only the function of hemoglobin concentration but of tube properties.

This problem may be solved by an additional calibration injection of the same indicator, which is injected in the arterial line, but upstream of the place where the measurements are made. The equation for this case will be:

$$Q_{dial} = V_{cal} / S_{cal} \qquad \text{(Eq. 4)}$$

where V_{cal} is the known quantity of indicator in the calibration injection and S_{cal} is the area under the resulting dilution curve. This area is the average concentration of indicator in the blood for the duration of the curve, times the duration of the curve.

From Equations 2 and 4 the formula for shunt blood flow will be:

$$Q_{shunt} = Q_{dial} \left(\frac{V_{ven}}{V_{cal}} * \frac{S_{cal}}{S_{art}} - 1 \right) \qquad \text{(Eq. 5)}$$

or

$$Q_{shunt} = \left(\frac{V_{ven}}{S_{art}} - \frac{V_{cal}}{S_{cal}} \right) \qquad \text{(Eq. 6)}$$

Equation 5 is suitable if blood flow in the tube can be measured accurately. The ratio S_{cal}/S_{art} shows that the recorded dilution areas only need to be proportional to relative changes in concentrations in this case. Assuming that tube properties are constant during the measurements, the value of this ratio can be calculated with high accuracy for most type of sensors, including sound velocity, optical, etc.

Equation 6 can be used where tube blood flow is unknown but absolute concentrations are measured, for instance by withdrawing the blood from the arterial blood line and using an optical densitometer for optical dye dilution measurements.

To avoid the need for a calibration injection, an additional sensor that is matched to the arterial line sensor is located on the venous line downstream of the location of the intravenous indicator injection. For this case, the injected indicator will be mixed with the venous line tube flow, so by analogy with the calibration injection of Equation 4:

$$Q_{dial} = V_{ven} / S_{ven} \qquad \text{(Eq. 7)}$$

where S_{ven} is the area under the dilution curve and is calculated as the average concentration of indicator in the blood for the duration of curve, times the duration of the curve. From the same injection, the area S_{art} is generated. The formula for blood flow by substituting in Equation 5 is:

$$Q_{shunt} = Q_{dial} \left(\frac{S_{ven}}{S_{art}} - 1 \right) \qquad \text{(Eq. 8)}$$

As an alternative to the foregoing, a measurement of the quantity of blood recirculation may be made during a normal connection of the dialysis blood lines of the shunt, with the intake to the arterial line being upstream in the shunt and the outlet of the venous line connection being downstream in the shunt. With this "normal" connection, after injecting an indicator into the venous line, a rapid appearance of indicator

in the arterial line is an indication that recirculation exists. The quantity of recirculation is the fraction of freshly filtered blood in the venous line that recirculates to the arterial line and this quantity is equal to the ratio of indicator volume that is recirculated into the arterial line (V_{rec}) to the volume that was injected into the venous line (V_{ven}).

The amount of recirculated indicator V_{rec} is equal to the area under the recirculated concentration dilution curve S_{rec} multiplied by the dialysis blood flow in the arterial line Q_{dial}:

$$V_{rec} = S_{rec} * Q_{dial} \qquad \text{(Eq. 9)}$$

The same problem with the evaluation of S_{rec} that was described for Equations 2 and 3 persists; namely, the difficulty of measuring indicator concentration through the tubing. This problem is avoided by an additional calibration injection of the same indicator into the arterial line upstream from the place where the measurements are made, as discussed above with respect to Equation 4. From Equations 4 and 9 the recirculating fraction is:

$$\frac{V_{rec}}{V_{ven}} = \frac{V_{cal}}{V_{ven}} * \frac{S_{rec}}{S_{cal}} \qquad \text{(Eq. 10)}$$

The ratio S_{rec}/S_{cal} in Equation 10 indicates that the measured dilution areas need only be in the same relative units. Assuming that tube properties are constant during the measurements, this ratio can be calculated with high accuracy for most types of sensors; e.g., sound velocity, optical, etc.

To avoid the need for a calibration injection, an additional sensor that is matched to the arterial line sensor may be located on the venous line downstream of the location of the intravenous indicator injection. For this case, the injected indicator will be mixed with the venous line flow, so by analogy with the calibration injection Equation 7:

$$\frac{V_{rec}}{V_{ven}} = \frac{S_{rec}}{S_{ven}} \qquad \text{(Eq. 11)}$$

In summary, the, shunt blood flow can be measured by reversing arterial and venous blood lines. An arterial inlet, which removes blood from a patient's vascular system, is located in the shunt downstream of a venous outlet, which returns treated blood to the patient's vascular system. An indicator material is injected into an injection port in the venous tube, and changes in the physical properties of the blood are monitored in the arterial line. These changes are recorded, with the area under the resulting dilution curve providing a measure of blood flow in the shunt and tube line. The indicator used for this purpose is any material or blood treatment which changes the physical characteristics of the blood. For example, it can be a saline solution, preferably of known concentration, or can be a heating or cooling of a quantity of blood. The change of characteristics is measured by known sensors, such as sound velocity sensors, electrical impedance sensors, optical sensors, thermal sensors, isotope sensors, or the like, and the blood flow relationships are calculated in accordance with the foregoing equations.

Because the tubing used to carry blood from the patient to the dialysis equipment introduces errors into the measurements of blood flow, calibration measurements may be required, using a calibration injection and, if blood flow is unknown, blood concentration measurements. To avoid the need for a calibration injection, an additional sensor may be provided on the venous line downstream of the venous injection port.

Blood recirculation can also be measured with the arterial inlet located in the shunt upstream of the venous outlet. In this case, the indicator is injected into an injection port in the venous line outlet (as before) and the blood characteristics are monitored in the arterial line. A calibration injection may be provided at an injection port in the arterial line upstream of the arterial tube monitor or, to avoid a calibration injection, a second blood characteristic monitor can be provided in the venous tube downstream of the venous injection port.

Brief Description of the Drawings

The foregoing, and additional objects, features, and advantages of the present invention will become apparent to those of skill in the art from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a diagrammatic illustration of an arterio-venous shunt connected by way of arterial and venous tubes to a dialyzer with an arterial tube inlet in the shunt downstream from

a venous tube outlet, an injection port in the venous tube, and a sensor for the arterial tube;

Fig. 1A illustrates a dilution curve for the device of Fig. 1;

Fig. 2 is a modification of Fig. 1, adding a second sensor for the arterial tube;

Fig. 3 is a second modification of Fig. 1, adding an injection port in the arterial tube, upstream of the arterial sensor;

Fig. 3A illustrates a dilution curve for the device of Fig. 3;

Fig. 4 is a third modification of Fig. 1, adding to the device of Fig. 3 a second arterial sensor of the type illustrated in Fig. 2;

Fig. 5 is a fourth modification of Fig. 1, incorporating two additional sensors, one for each of the venous and arterial tubes;

Figs. 5A and 5B illustrate dilution curves for the device of Fig. 5;

Fig. 6 is a diagrammatic illustration of a second embodiment of the invention, illustrating an arterio-venous shunt connected by way of arterial and venous tubes to a dialyzer, with an arterial tube inlet in the shunt upstream of a venous tube outlet, an injection port in the venous tube, a sensor for the arterial tube and a calibration port in the arterial tube upstream of the sensor; and

Fig. 7 is a diagrammatic illustration of a modification of the device of Fig. 6, wherein the calibration port of Fig. 6

is replaced by a venous tube sensor downstream of the venous tube injection port.

Description of Preferred Embodiments

Turning now to a more detailed consideration of the process of determining blood flow in a dialysis shunt in accordance with the present invention there is illustrated in Fig. 1 a patient blood dialysis system 10 utilizing a reversed connection of arterial and venous lines to a blood vessel 12 illustrated as an arterio-venous shunt connected at its upstream end 14 to a patient's artery 16 and connected at its downstream end 18 to a patient's blood vein 20. The shunt may be an artificial vessel or a native vessel that is surgically moved between artery 16 and vein 20. The direction of flow of blood in the vessel 12 is indicated by arrow 22 and it is this blood flow which is to be determined. Connected between vessel 12 and conventional blood dialysis equipment 24 is an arterial line, or tube 26 having an inlet 28 in the shunt 12 for drawing blood for treatment by the dialysis equipment. The direction of flow of blood in arterial line 26 is illustrated by arrow 30.

Also connected between the dialysis equipment 24 and shunt 12 is a venous line, or tube, 32 which carries treated blood from the dialysis equipment 24 back to the shunt. The venous line 32 has an outlet 34 located in shunt 12, upstream of the arterial line inlet 28. The direction of flow of treated blood in venous line 32 is illustrated by arrow 36. As illustrated by arrow 38, treated blood from the outlet 34 travels downstream, in the direction of the main flow 22, toward the

inlet 28 where some of the treated blood 38 is collected by the arterial line 26.

Measurement of blood flow in the shunt is obtained, in accordance with the invention, by injecting into venous line 32, as by way of an injection port 40, an indicator material having a selected physical property differing from that of the blood being treated. In the preferred embodiment, this material, indicated by arrow 42, is a saline solution which is isotonic with the blood but which has different sound velocity properties. Other indicator materials may be, for example, heated or cooled blood. The injected indicator is mixed with the blood flow 36 in the venous line and is returned to shunt 12 where it is mixed with the shunt flow 22. A portion of the indicator is withdrawn from the shunt by the arterial blood line, as indicated by arrow 30.

A sensor 50 is provided at a location downstream of the injection port 40, and preferably is located in the arterial line 26, as illustrated in Fig. 1. The sensor preferably is a blood sound velocity detector which comprises a sound source 52 sending a sound beam directly through the blood passing through arterial line 26 to a sound receiver 54 which produces an output signal related to the velocity of sound in the blood. Such sound velocity sensors are well known in the art and are exemplified by the Transonic 4x perivascular probe manufactured by Transonic Systems, Inc., Ithaca, New York, U.S.A. In this probe, the receiver 54 produces an output signal on line 56 which is directed to a detector 58 which measures and evaluates the signal supplied by way of line 56. The detector records the signal and

carries out the calculations described above for converting the sensor output signal to a blood concentration signal for determination of the blood flow in the shunt 12 and through the dialysis equipment 24. If the blood flow in the dialysis equipment 24 is relatively small in comparison to the flow in shunt 12, the measurements made by sensor 50 will give results which over state the flow of the shunt.

More particularly, the blood flow Q in shunt 12 may be calculated in accordance with Equation 1 by calculating the area under the dilution curve obtained by sensor 50. An example of such a curve is illustrated in Fig. 1A, wherein the velocity of sound in the arterial blood flow is illustrated by curve 59. At time 0 an indicator material is injected at port 40, and at some later time, the change in sound velocity caused by the indicator is detected at sensor 50, as illustrated by the dip, or dilution area, 59a in curve 59. The area under the dilution curve 59 in region 59a is the area S_{art} described in Equation 2.

As illustrated in Fig. 2, a second blood flow sensor 60 may be provided on arterial line 26 and connected by way of line 62 to the detector 58. This second sensor is a blood flow sensor such as a model HT109 clamp-on flowmeter produced by Transonic Systems, Inc., and is used to measure the blood flow Q_{dial} in line 26 so that it can be subtracted from the sum of flows calculated in accordance with the embodiment of in Fig. 1 to increase the accuracy of the shunt blood flow determination. This improved accuracy is obtained in accordance with Equations 2 and 3. Although sensor 60 is shown as separate from sensor 50,

the two sensors may be incorporated into a single unit, if desired.

Another modification of the invention is illustrated in Fig. 3, which is the same as Fig. 1 but with the addition of an injection port 70 in the arterial line 26 for injecting a calibration indicator material, shown by line 72. This injection port 70 is located upstream of the sensor 50 so that the indicator material 72 is mixed with all of the blood flow in line 26. The injection of the calibration indicator material in port 70 produces a corresponding dilution curve illustrated at 74 in Fig. 3A in accordance with the change in sound velocity in the blood, as sensed by sensor 50, and this dilution curve is recorded by detector 58. The detector determines the blood flow Q_{dial} in line 26 from the area S_{cal} under curve 74 and from the known volume V_{cal} of indicator material 72, in accordance with equation 4. This blood flow Q_{dial} is then subtracted from the sum of flows calculated in accordance with Fig. 1 to increase the accuracy of the shunt blood flow measurement, in accordance with Equation 6.

Another embodiment of the invention is illustrated in Fig. 4, which includes all of the measurements of Figs. 1, 2, and 3. Thus, the device of Fig. 4 includes sensor 50 with a sound source 52 and a sound receiver 54 supplying signals on line 56 to detector 58, includes a blood flow sensor 60 connected by way of line 62 to detector 58, and includes a calibration injection port 70 for receiving calibration indicator material 72. The output signal on line 62 is for measuring the dialysis blood flow Q_{dial}. The indicator 72 is a calibration injection, as described

above, and relative changes of sound velocity related to known blood flow Q_{dial} are measured by sensor 50. The relative changes of sound velocity corresponding to injections made into port 40 of indicator material 42 and into port 70 of the same indicator material 72 are recorded by sensor 50, so that relative changes of sound velocity in arterial line 26 due to these injections can be calculated in detector 58 to obtain an accurate shunt blood flow measurement in accordance with equation 5.

Still another embodiment of the invention is illustrated in Fig. 5, which is similar to the embodiment of Fig. 2 but with the addition of a sensor 80 located on the venous line, or tube, 32. Sensor 80 includes a sound transmitter 82 and a sound receiver 84, the receiver producing an output signal on output line 86 which is connected to detector 58. The use of sensor 80 avoids the need for additional calibration injections in arterial line 26. The additional sound velocity source 82 and receiver 84 match the sound velocity source 52 and receiver 54, and sensor 80 is located downstream of the injection port 40 in venous line 32. As a result, all of the indicator material 42 flows through sensor 80, producing dilution curve 88 (Fig. 5A). The injection made in port 40 is mixed only with the blood flow in venous line 32, and thus serves to calibrate the sensor 80. The same injection later generates dilution curve 89 in the matching sensor 50 (Fig. 5B) after the indicator material passes through the shunt vessel 12, and a portion is recirculated into arterial line 26. The calculation of shunt blood flow Q_{shunt} is then made in accordance with Equation 8.

A second embodiment of the invention is illustrated in Fig. 6, to which reference is now made. This embodiment provides a measurement of undesired recirculation of freshly purified blood while utilizing a "normal" connection of the dialysis equipment lines. Thus, in this embodiment the dialysis equipment 24 is connected to a patient's vascular system by way of shunt 12 and an arterial line 90 leading from inlet 92 to the dialysis equipment. Similarly, the equipment is connected to shunt 12 by venous line 94 which delivers purified blood from the dialysis equipment through outlet 96 in the shunt. The direction of blood flow in arterial line 90 is illustrated by arrow 98, and the direction of blood flow in venous line 94 is illustrated by arrow 100.

Although the outlet 96 is downstream from the inlet 92 in shunt 12, nevertheless such a "normal" connection can produce undesired recirculation of purified blood, as illustrated by arrow 102. Thus, purified blood can flow upstream in vein 12 and be picked up at inlet 92 for recirculation through the dialysis equipment, such recirculated blood then making up a part of the arterial blood flow 98.

To measure this recirculation, an indicator material having a selected physical property differing from that of the blood is injected into the venous line 94 through an injection port 104. In the preferred embodiment, the indicator material, indicated by arrow 106, is a saline solution isotonic with the blood, but having different sound velocity properties. The injection of such an indicator dilutes the blood in venous line 94, and if recirculation exists, some of the diluted blood will

appear in arterial line 90, producing resultant sound velocity changes which will be recorded by a sensor 110 having a sound source 112 and a sound receiver 114. The receiver 114 is connected by way of line 116 to a detector 118 of the type described in the previous embodiment. The detector serves like as a measuring and evaluating device which records the received signals which calculates the area under the dilution curve which results from the injection of the indicator material, and which carries out the calculations prescribed by the equations described above.

An additional calibration injection of indicator material 120 which is the same as the indicator material 106, may be injected by way of a port 122 in arterial line 90, upstream of the sensor 110. Since all of the blood in the arterial line 90 will pass through the sensor 110, the indicator material injected at 122 will be mixed only with this arterial blood flow, and the resulting dilution curve recorded by detector 118 permits calibration of the system by calculating the area under the dilution curve and subsequent determination of the recirculation fraction in accordance with Equation 10.

If it is desired to avoid the need for a recalibration injection, a modified version of the device of Fig. 6 may be provided, as illustrated in Fig. 7. In this modification, an additional sensor 130 having a sound velocity source 132 and a sound velocity receiver 134 is provided on the venous line 94. The receiver 134 is connected by way of line 136 to the detector 118. The sensor 130 matches sensor 110 and is located downstream of the injection port 104, so that all of the blood from the

dialysis equipment 24 as well as the indicator material 106 injected in port 104 will pass through sensor 130. The sensor measures the dilution curve in the arterial blood 100, and the same injection then produces a dilution in the flow 98 through arterial line 90. Sensor 110 detects the indicator material to provide a resulting signal to detector 118 from which the recirculation can be calculated in accordance with Equation 11, as outlined above with respect to the first embodiment and the various modifications thereof described with reference to Figs. 1-5.

Although the present invention has been described in terms of preferred embodiments, it will be understood that variations and modifications may be made without departing from the true spirit and scope thereof.

WHAT IS CLAIMED IS:

1. In a blood dialysis system including a dialyzer, an inlet arterial line from an arterio-venous blood dialysis shunt to the dialyzer and an outlet venous line from the dialyzer to the shunt, a process for determining blood flow in the shunt comprising:

removing blood from an arterio-venous shunt in a patient by way of an arterial line having an inlet at a downstream portion of said shunt;

delivering the blood in said arterial line to a dialyzer;

delivering the blood from the dialyzer to said shunt through a venous line having an outlet at an upstream portion of said shunt;

changing a selected physical property of said blood in said venous line to produce a distinguishable blood characteristic;

monitoring said selected physical property with a sensor for said arterial line to determine the presence of blood having said changed physical property in said arterial line;

measuring the amount and duration of said changed physical property in said arterial line and producing a dilution curve from said measurement; and

determining from the area of said dilution curve the blood flow in said arterio-venous shunt.

2. The process of claim 1, wherein the step of changing a physical property of said blood comprises injecting an indicator material into said venous line.

3. The process of claim 1, wherein the step of changing a physical property of said blood comprises changing the velocity of sound in said blood.

4. The process of claim 1, wherein the step of changing a physical property of said blood comprises changing the electrical impedance of said blood.

5. The process of claim 1, wherein the step of changing a physical property of said blood comprises changing the optical characteristics of said blood.

6. The process of claim 1, wherein the step of changing a physical property of said blood comprises changing the thermal characteristics of said blood.

7. The process of claim 1, further including measuring the blood flow in said arterial line to provide increased accuracy in the determination of said shunt blood flow.

8. The process of claim 1, further including further changing said selected physical property of said blood in said arterial line prior to said monitoring step.

9. The process of claim 8, further including additionally monitoring blood flow in said arterial line;

measuring said arterial line blood flow; and

determining from said measured arterial line blood flow and said area of said dilution curve the blood flow in said arterio-venous shunt with increased accuracy.

10. The process of claim 1, further including monitoring said selected physical property with a sensor for said venous line matched with said sensor for said arterial line;

measuring from said venous line sensor relative changes of said selected physical property; and

determining from the measurements by said venous line sensor and said arterial line sensor the blood flow in said arterio-venous shunt.

11. In a blood dialysis system including a dialyzer, an inlet arterial line extending from an arterio-venous blood dialysis shunt to the dialyzer, and an outlet venous line extending from the dialyzer to the shunt, a process for determining the recirculation of blood through the shunt, comprising:

removing blood from the arterio-venous shunt by way of an arterial line having an inlet at an upstream portion of said shunt;

delivering the blood in said arterial line to a dialyzer;

delivering the blood from the dialyzer to said shunt through a venous line having an outlet at a downstream portion of said shunt;

changing a selected physical property of said blood in said venous line to produce a distinguishable blood characteristic;

monitoring the blood at a preselected location in said arterial line to measure changes of said physical property

of said blood due to said changing of said physical property to produce a corresponding first dilution curve;

additionally changing said selected physical property of said blood in said arterial line upstream of said preselected location to produce said distinguishable blood characteristic;

additionally monitoring the blood at said preselected location in said arterial line to measure changes of said physical property of said blood due to said additional changing of said physical property to produce a corresponding second dilution curve; and

determining from said first and second dilution curves the blood recirculation to said dialyzer.

12. In a blood treatment system including a dialyzer, an inlet arterial line extending from an arterio-venous blood dialysis shunt to the dialyzer, and an outlet venous line extending from the dialyzer to the shunt, a process for determining blood recirculation through the shunt to the dialyzer, comprising:

removing untreated blood from an upstream location in a dialysis shunt in a patient and directing the blood through a dialyzer;

returning treated blood from the dialyzer to a downstream location in the shunt;

inserting a first indicator into said returning blood;

monitoring said untreated blood to detect the presence of said first indicator in the untreated blood;

determining the amount of first indicator in the untreated blood and the duration of time the first indicator is present in said untreated blood;

inserting a second indicator into said untreated blood;

monitoring said untreated blood to detect the presence of said second indicator in the untreated blood;

determining the amount of said second indicator and the duration of time the second indicator is present in said untreated blood; and

determining from the amount and duration of said first and second indicators the amount of blood recirculation.

13. In a blood dialysis system, apparatus for measuring blood flow in a dialysis shunt, comprising:

a dialyzer for treating blood;

an arterial line connectable between the dialyzer and a first location in a dialysis shunt carrying a flow of untreated blood for transporting untreated blood to the dialyzer;

a venous line connectable between the dialyzer and a second location in the dialysis shunt upstream from said first location for directing treated blood from the dialyzer to the shunt wherein the treated blood is mixed with untreated blood in the shunt;

an injection prot in said venous line for injecting an indicator into said treated blood;

an indicator sensor on said arterial line for detecting the amount and duration of said indicator in said untreated blood; and

a detector responsive to the amount and duration of said indicator in said arterial line for determining the blood flow in said shunt.

14. The apparatus of claim 13, further including a second injection port in said arterial line for injecting a calibration indicator into said untreated blood upstream of said sensor.

15. The apparatus of claim 14, further including a blood flow sensor on said arterial line.

16. The apparatus of claim 13, further including a blood flow sensor on said arterial line.

17. The apparatus of claim 16, further including a second indicator sensor on said venous line downstream of said venous line injection port for detecting said indicator in said venous line.

18. In a blood dialysis system, apparatus for measuring blood recirculation comprising:

a dialyzer for treating blood;

an arterial line connected between the dialyzer and a first location in a dialyzer shunt carrying a flow of untreated blood for transporting untreated blood to the dialyzer;

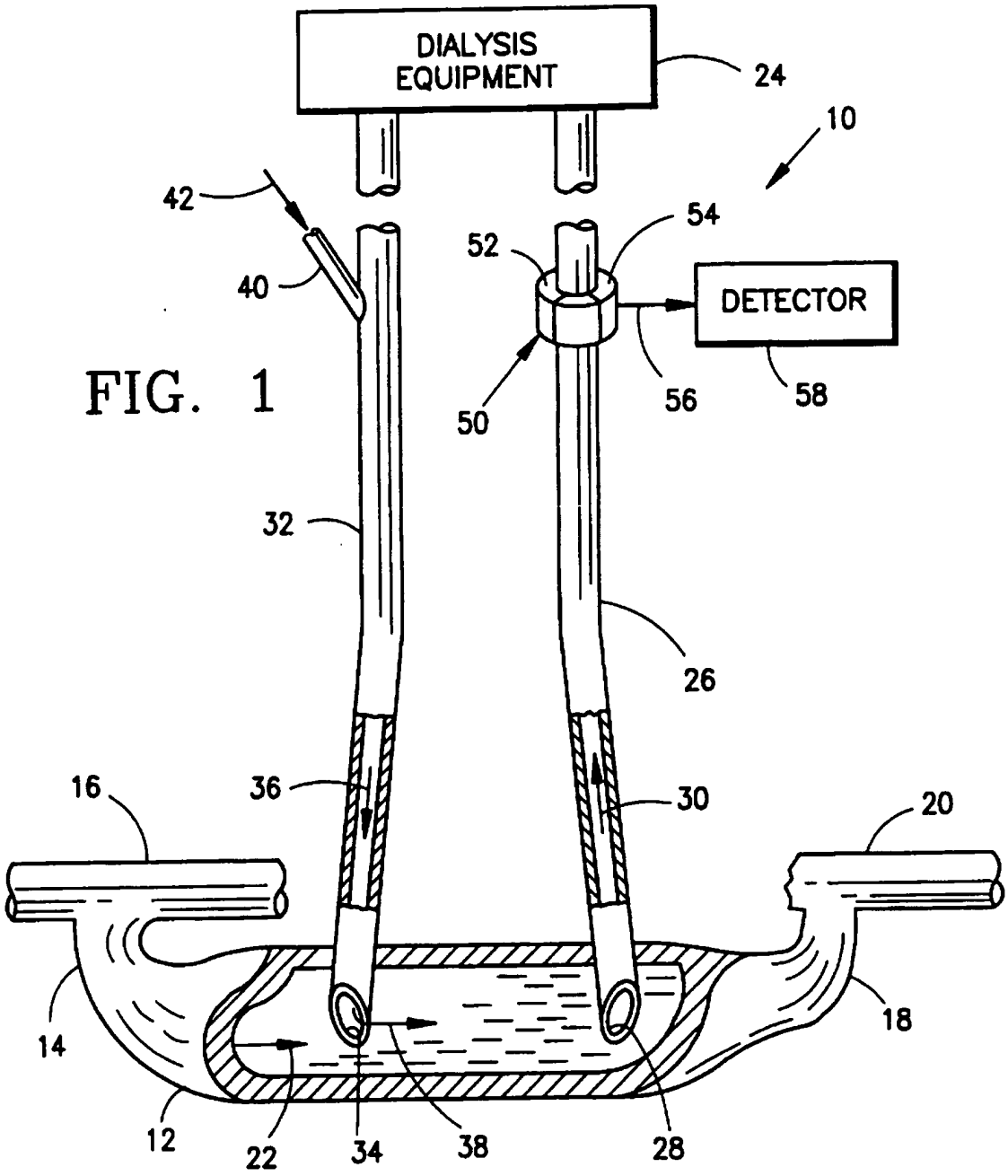
a venous line connected between the dialyzer and a second location in the dialyzer shunt downstream from said first location for directing treated blood from the dialyzer to the shunt where the treated blood is mixed with untreated blood in the shunt;

a first injection port in said venous line for injecting an indicator into said treated blood;

an indicator sensor in said arterial line for detecting the amount and duration of said indicator in said untreated blood;

a second injection port in said arterial line upstream of said indicator sensor for injecting a second indicator into said arterial line, said indicator sensor detecting the amount and duration of said second indicator in said untreated blood; and

a detector responsive to said indicator sensor for determining from the amount and duration of said first and second indicators the amount of blood recirculation in said system.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42
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54
DETECTOR
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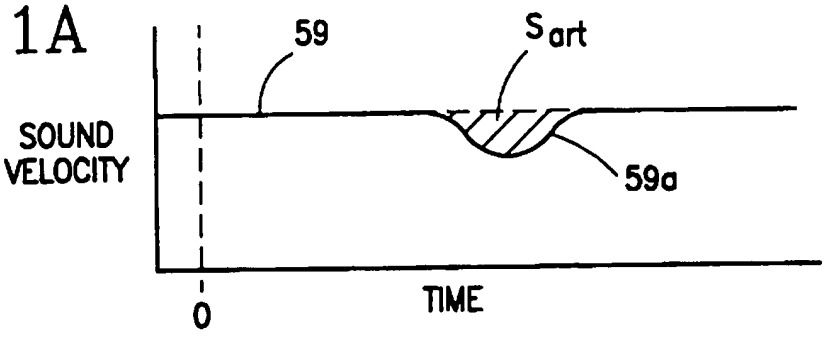
38
28

FIG. 1


59
S art
SOUND VELOCITY
59a
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TIME

FIG. 1A

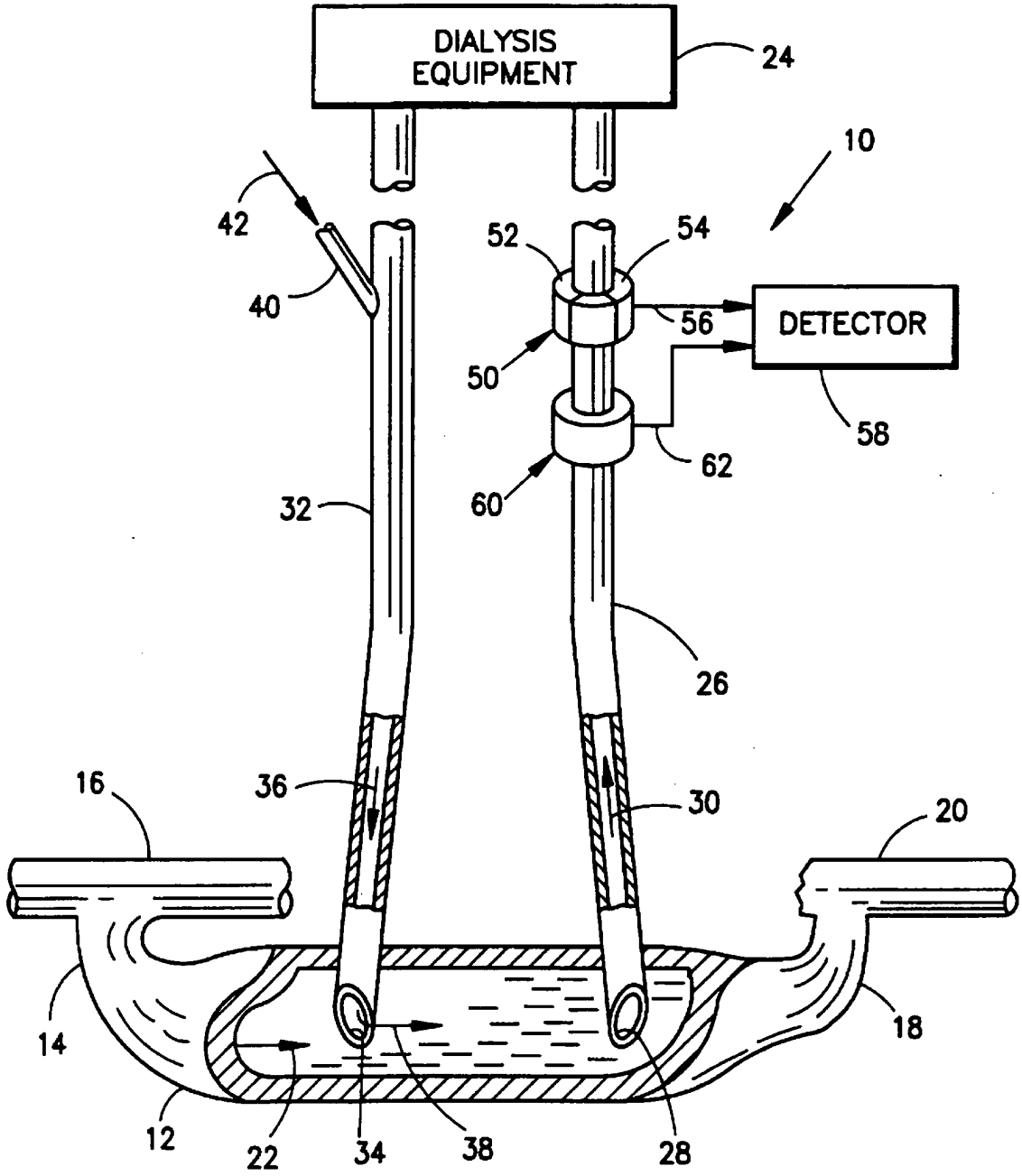
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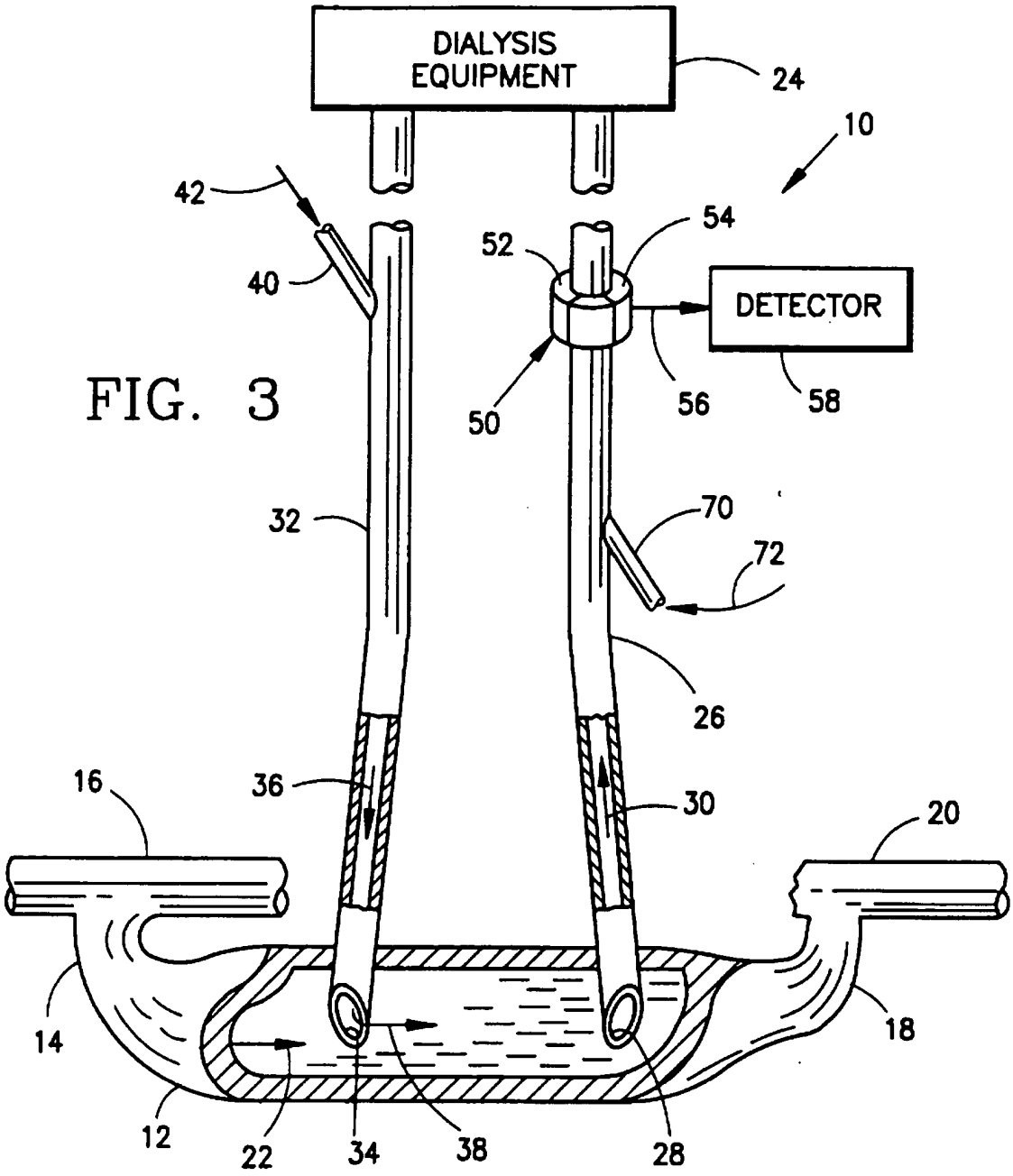
FIG. 2

FIG. 3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DETECTOR
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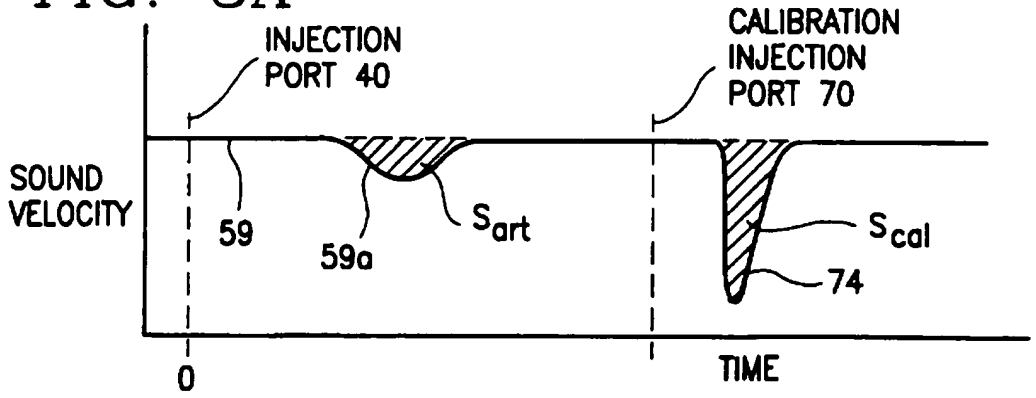
FIG. 3A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CALIBRATION INJECTION PORT 70
SOUND VELOCITY
59
59a
S_{art}
S_{cal}
74
0
TIME

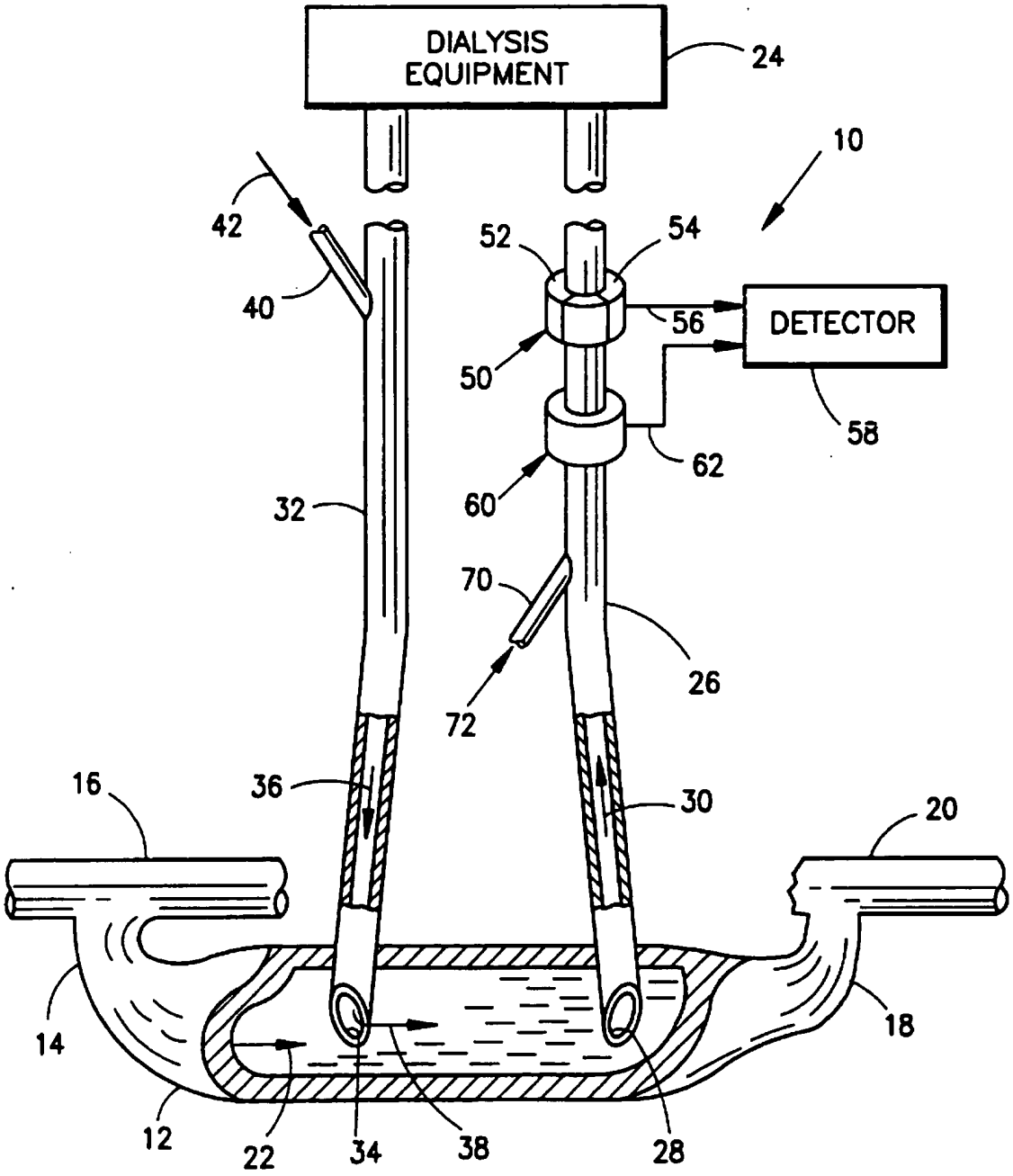
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FIG. 4

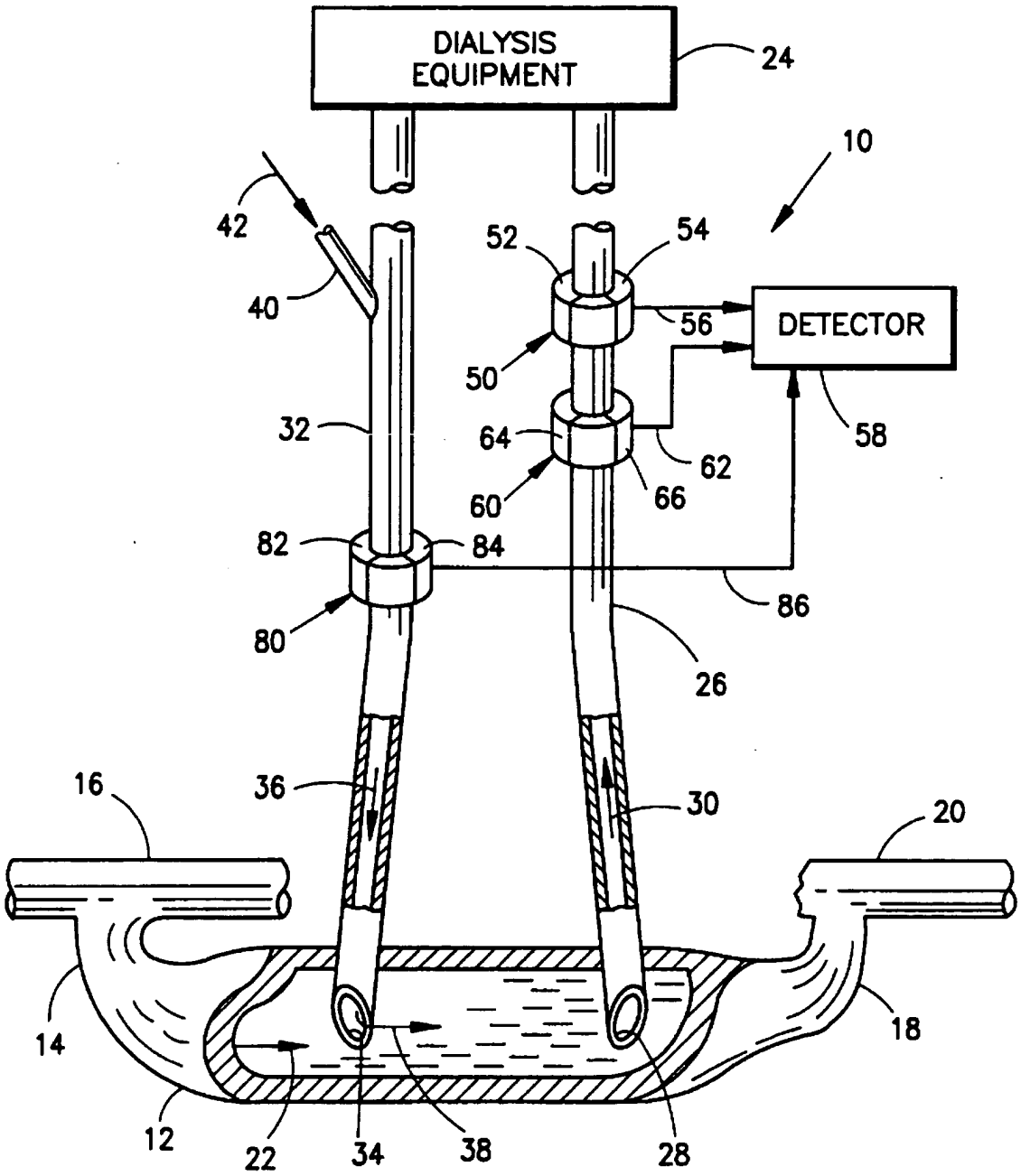
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FIG. 5

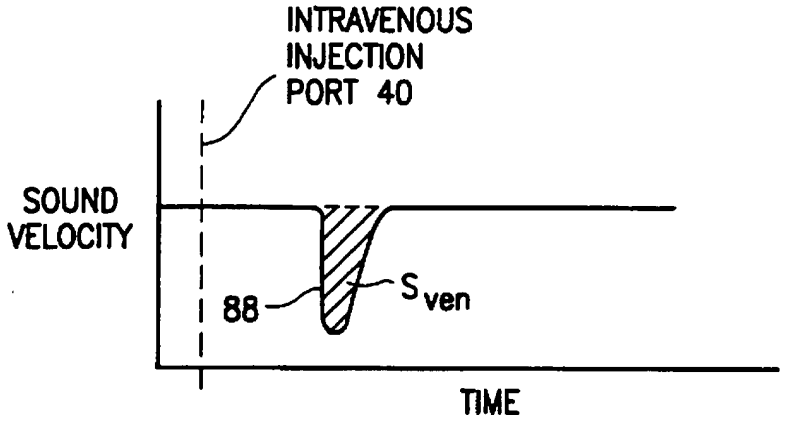
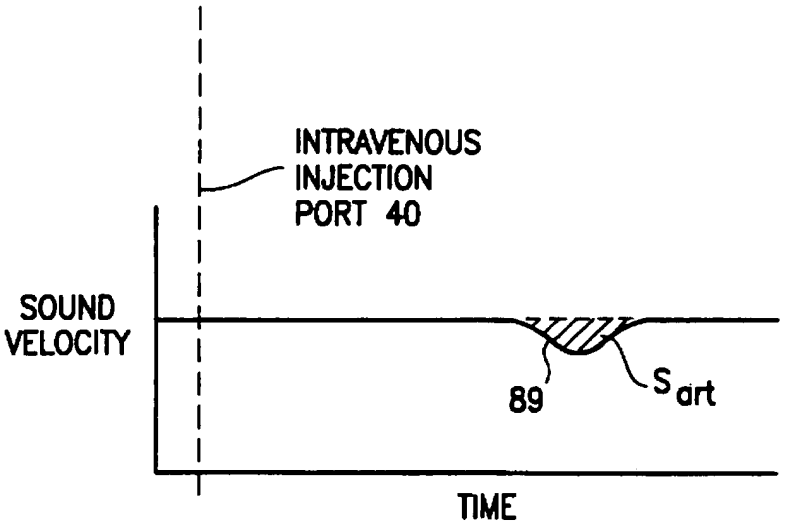

INTRAVENOUS
INJECTION
PORT 40
SOUND
VELOCITY
88
S ven
TIME

FIG. 5A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INJECTION
PORT 40
SOUND
VELOCITY
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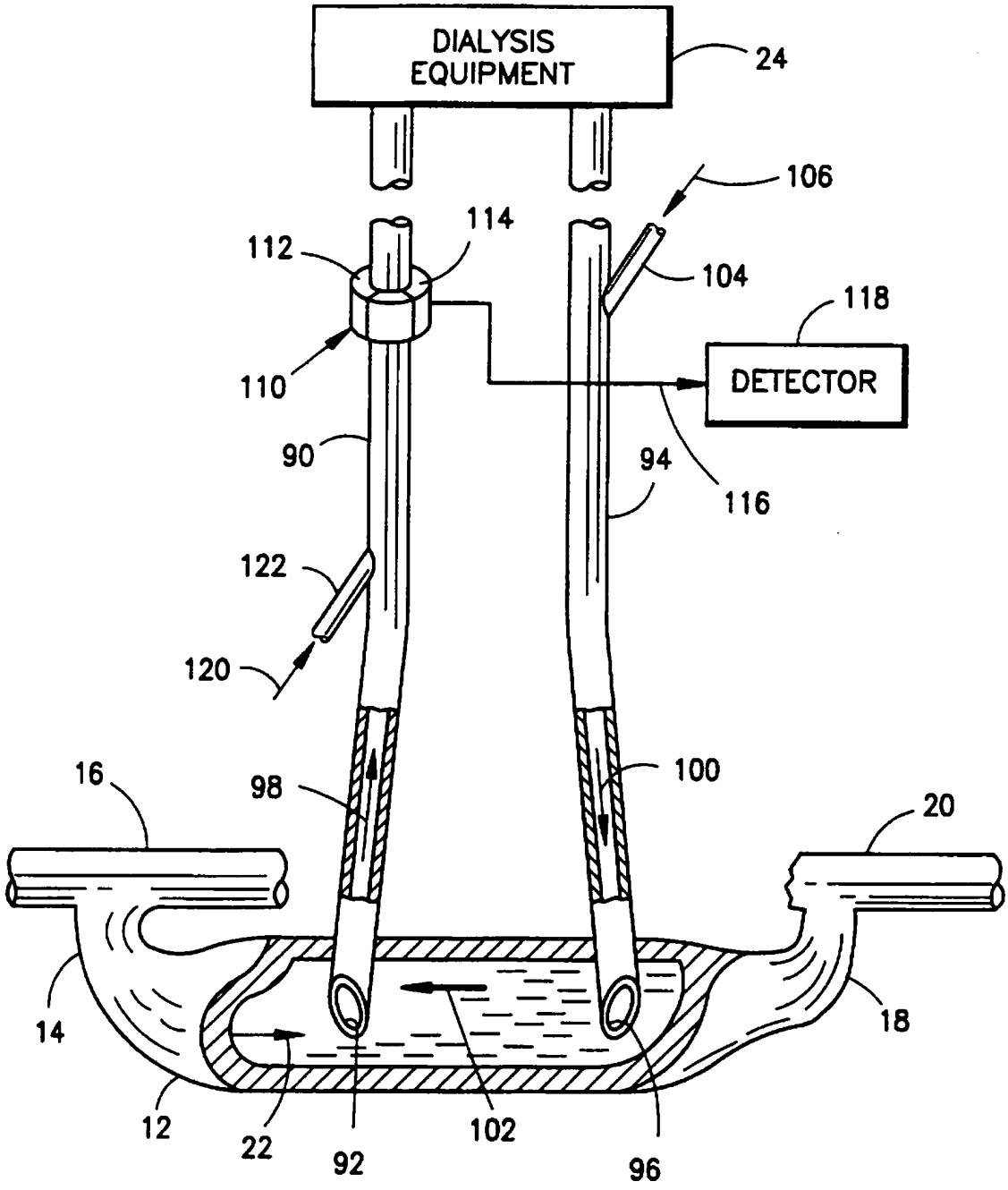
S art
TIME

FIG. 5B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96

FIG. 6

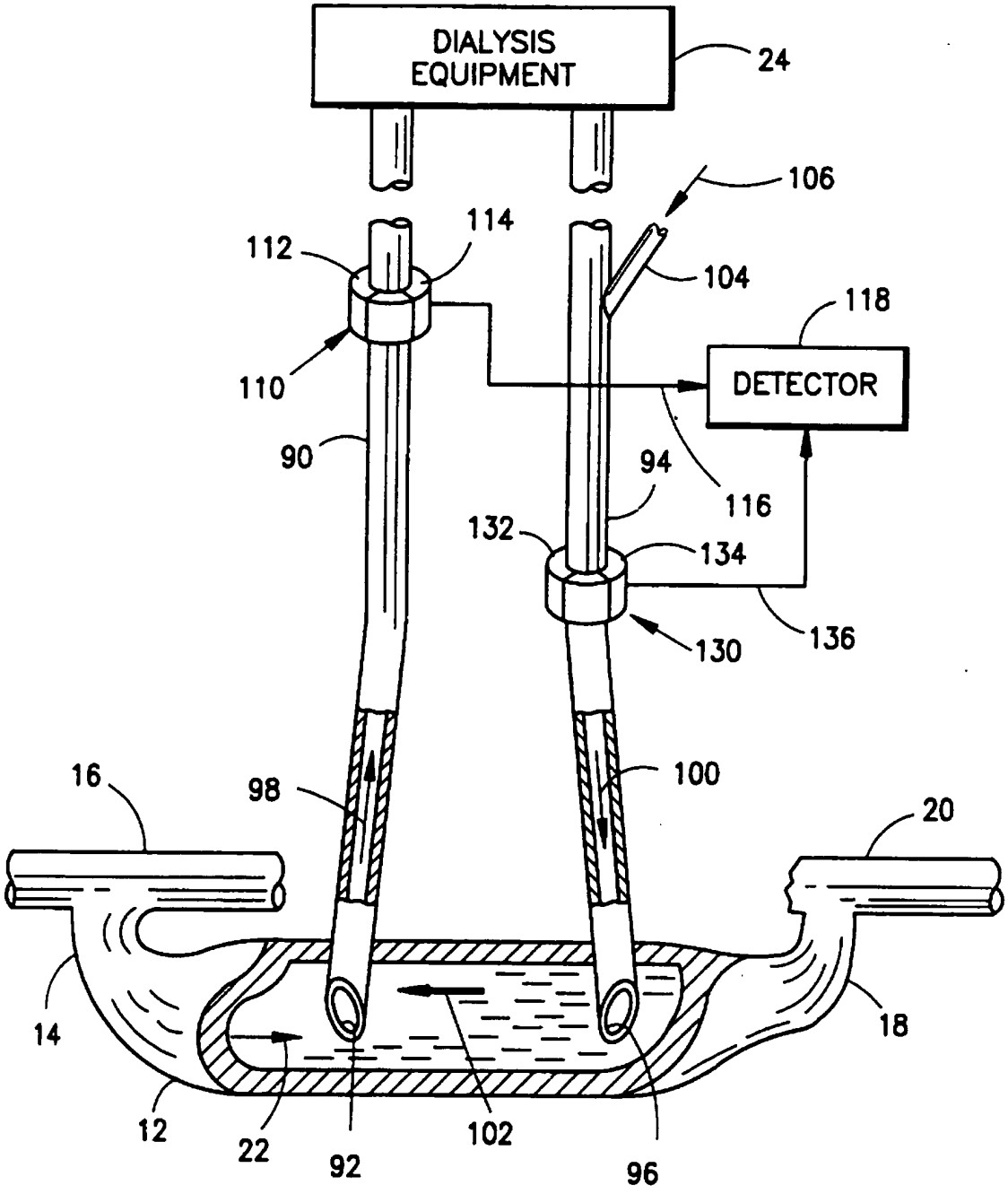
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FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13163

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01D 61/32
US CL :Please See Extra Sheet.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/645, 646, 739, 742, 745, 746, 805, 85, 93, 96.1, 96.2, 97, 103, 321.6; 436/ 56, 164; 604/4, 5, 6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,312,550 (HESTER) 17 MAY, 1994, SEE ENTIRE DOCUMENT	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 09 FEBRUARY 1995	Date of mailing of the international search report 20 MAR 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SUN UK KIM Telephone No. (703) 308-2350

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13163

A. CLASSIFICATION OF SUBJECT MATTER:
US CL :

210/645, 646, 739, 782, 745, 746, 805, 85, 93, 96.1, 96.2, 97, 103, 321.6; 436/ 56, 164; 604/4, 5, 6